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ГОСУДАРСТВЕННЫЙ КОМИТЕТ
ПО ИЗОБРЕТЕНИЯМ И ОТКРЫТИЯМ
ПРИ ГИИТ СССР

ОПИСАНИЕ ИЗОБРЕТЕНИЯ

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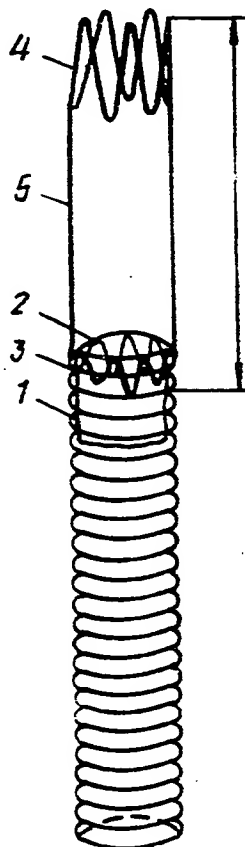
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(53) 615.475(088.8)

(56) Авторское свидетельство СССР № 1217402, кл. А 61 F 2/06, 1984.

(54) САМОФИКСИРУЮЩИЙСЯ ПРОТЕЗ КРОВЕНОСНОГО СОСУДА

(57) Изобретение относится к медицине и позволяет предупредить миграцию протеза кровеносного сосуда путем снабжения его дополнительным фиксирующим элементом 4, размещенным вне эластичной оболочки 1 и соединенным с основным фиксирующим элементом 3, закрепленным на внутренней стенке оболочки 1 посредством упругих стержней 5. Общая высота дополнительного и основного фиксирующих элементов 3 и 4, а также упругих стержней 5 вдоль оси протеза составляет не менее $2d$, где d — внутренний диаметр сосуда. Упругие стержни выполняются прямыми или изогнутыми в сторону оси протеза. 2 ил.



фиг. 1

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Изобретение относится к медицинской технике и касается непосредственно усовершенствования самофиксирующегося протеза кровеносного сосуда, используемого для замещения пораженных участков аорты и магистральных артерий при аневризмах, атеросклерозе, ранении или расслаивании.

Целью изобретения является предупреждение миграции протеза.

На фиг. 1 изображен протез кровеносного сосуда, общий вид; на фиг. 2 — схема размещения протеза в сосуде.

Протез состоит из эластичной оболочки 1, на внутренней поверхности которой нитями 2 закреплен основной фиксирующий элемент 3, выполненный в виде плоской изогнутой пружины зигзагообразной формы, свернутой в кольцо. Высота этого элемента выбирается в зависимости от длины здорового сегмента сосуда, в который он устанавливается и не превышает его. Протез снабжен также дополнительным фиксирующим элементом 4, выполненным по форме, аналогичной основному элементу 3, и соединенным с ним посредством упругих стержней 5. Дополнительный фиксирующий элемент 4 и упругие стержни 5 размещены вне оболочки. Общая высота H обоих фиксирующих элементов и соединяющих их упругих стержней 5 составляет не менее $2d$, где d — внутренний диаметр оболочки. В свою очередь длина упругих стержней 5 выбирается в зависимости от конфигурации сосуда. Выполнение высоты H фиксирующих элементов и упругих стержней менее $2d$ не обеспечивает устойчивого размещения протеза и не предотвращает его опрокидывания. Оптимальное количество

упругих стержней — два, диаметрально расположенные один относительно другого.

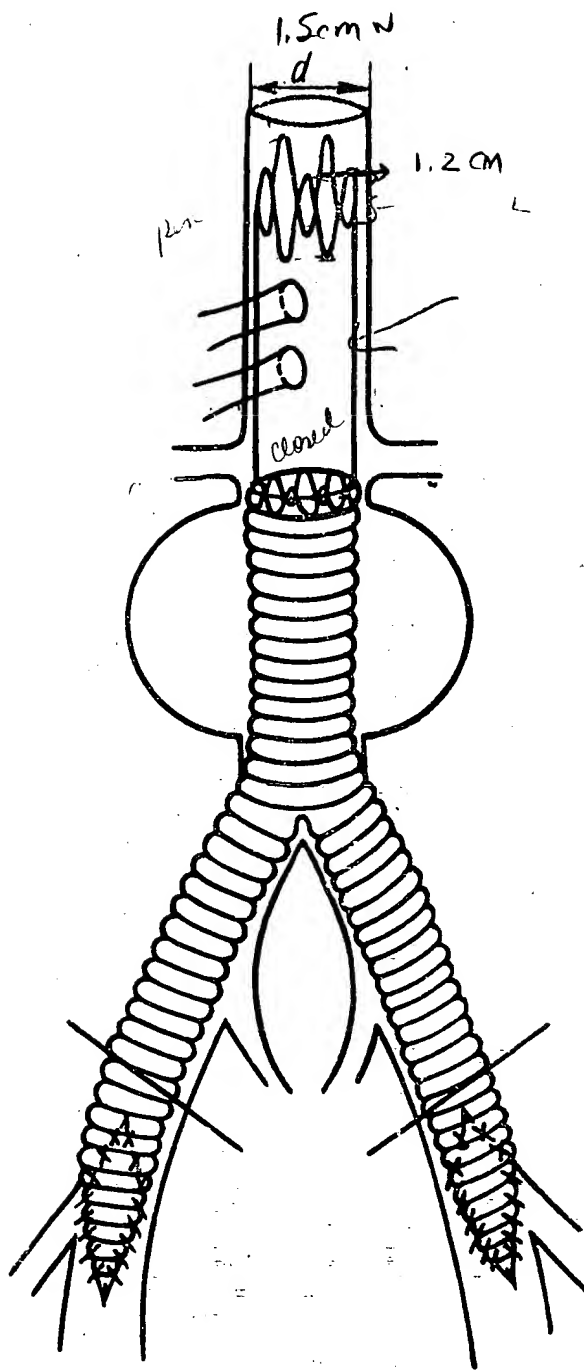
Протез устанавливают следующим образом.

Перед установкой оболочку 1 вместе с основным 3 и дополнительным 4 фиксирующими элементами сжимают в радиальном направлении до минимально возможного сечения и устанавливают во внутреннюю полость катетера, который вводят в необходимый сегмент сосуда. При выводе катетера из сосуда и одновременном удержании протеза неподвижным происходит распрямление оболочки протеза под действием фиксирующих элементов 3 до полного контакта ее со стенками сосуда. Основной фиксирующий элемент 3, окруженный каркасом протеза, контактирует с коротким неизменным участком сосуда, а дополнительный при этом контактирует с внутренней стенкой сосуда вне оболочки протеза.

Формула изобретения

Самофиксирующийся протез кровеносного сосуда, состоящий из эластичной оболочки с размещенным в ней фиксирующим элементом, выполненным в виде плоской изогнутой пружины зигзагообразной формы, отличающийся тем, что, с целью предупреждения миграции протеза, он снабжен дополнительным фиксирующим элементом аналогичной формы, который размещен вне оболочки и соединен с ней посредством упругих стержней, при этом общая высота фиксирующих элементов с упругими стержнями вдоль оси протеза составляет не менее $2d$, где d — внутренний диаметр оболочки.

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фиг. 2

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Производственно-издательский комбинат «Патент», г. Ужгород, ул. Гагарина, 101

FACSIMILE TRANSMITTAL LETTER

DATE: April 25, 2002

TO: Examiner Suzette Jackson

FAXED TO: (703) 308-2708

FROM: John S. Nagy, Esq.

RE: Application for U.S. Letters Patent
Serial No. 09/716,847
Divisional Application of USSN 09/136,982
Entitled: EXPANDABLE STENTS AND
METHOD FOR MAKING SAME
Filed: November 16, 2000
Inventors: Lau et al.
Our Docket No. ACS 56040

TOTAL NUMBER OF PAGES INCLUDING THIS PAGE: 7

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MESSAGE: Please see attached translation for U.S. Serial No. 09/716,847.

Please contact Jane Barnett (Grace) if there are any problems.

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TRANSLATION FROM RUSSIAN

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Invention Specifications for the Inventor's Certificate

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(53) UDC 615.475 (088.8)

(56) USSR Inventors Certificate No. USSR Patent No. 1217402, cl. A 61 F 2/06, 1984

(54) A SELF-FIXING PROSTHESIS FOR A BLOOD VESSEL

(57) The invention pertains to medicine and makes it possible to avoid migration of a prosthesis of a blood vessel by providing it with an additional fixing element 4, arranged outside an elastic shell 1 and joined to the main fixing element 3, attached to the inner wall of the shell 1 by means of elastic rods 5. The combined height of the additional and the main fixing elements 3 and 4, as well as the elastic rods 5, along the axis of the prosthesis is not less than $2d$, where d is the inner diameter of the vessel. The elastic rods are made straight or curved away from the axis of the prosthesis. Two illustration.

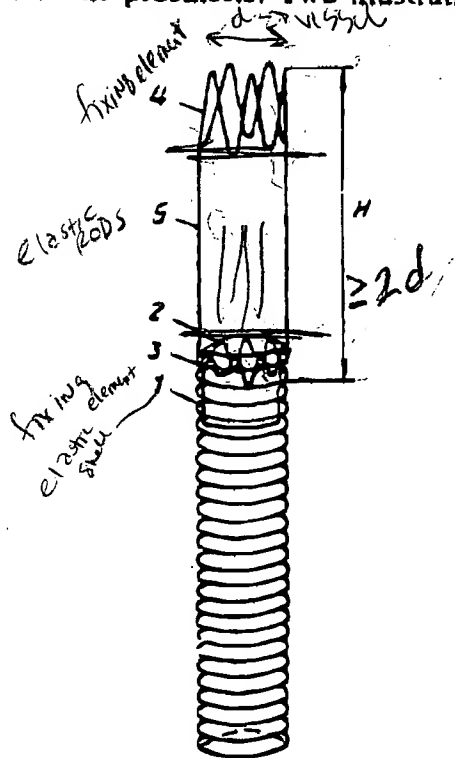


Fig. 1

The invention pertains to medical equipment and directly involves an improvement in the self-fixing prosthesis of a blood vessel used to replace damaged sections of the aorta and main arteries in cases of aneurism, atherosclerosis, wounds or exfoliation.

The purpose of the invention is to prevent migration of the prosthesis.

Figure 1 shows a prosthesis for a blood vessel, general view, and Fig. 2 a diagram of the arrangement of the prosthesis in the vessel.

The prosthesis consists of an elastic shell 1, on the inner surface of which threads 2 fasten a main fixing element 3 in the form of a flat, curved spring of zig zag shape, wound up into a ring. The height of this element is chosen in dependence on the length of the healthy segment of the vessel in which it is being placed and does not exceed this length. The prosthesis is also provided with an additional fixing element 4, whose shape is similar to that of the main element 3, being joined to it by means of elastic rods 5. The additional fixing element 4 and the elastic rods 5 are arranged outside the shell. The combined height H of both fixing elements and the elastic rods 5 which join them is not less than $2d$, where d is the inner diameter of the shell. In turn, the length of the elastic rods 5 is chosen in dependence on the configuration of the vessel. A height H of the fixing elements and elastic rods less than $2d$ does not ensure a stable arrangement of the prosthesis and does not prevent it from flipping over. The optimal number of elastic rods is two, diametrically opposite each other.

The prosthesis is inserted as follows.

Prior to insertion, the shell 1 along with the main 3 and additional 4 fixing elements is compressed in the radial direction to the minimum possible cross section and placed inside the inner cavity of a catheter, which is introduced into the necessary segment of the vessel. When the catheter is removed from the vessel, while at the same time holding the prosthesis immobile, the shell of the prosthesis straightens out under the action of the fixing elements 3 until it makes full contact with the walls of the vessel. The main fixing element 3, surrounded by the skeleton of the prosthesis, makes contact with the short unaltered segment of the vessel, while the additional fixing element makes contact with the inner wall of the vessel outside the shell of the prosthesis.

Patent Claims

A self-fixing prosthesis for a blood vessel, consisting of an elastic shell, inside which is arranged a fixing element in the form of a flat, curved spring of zig zag shape, characterized in that, in order to prevent migration of the prosthesis, it is furnished with an additional fixing element of similar shape, which is placed outside the shell and joined to it by means of elastic rods, the combined height of the fixing elements and the elastic rods along the axis of the prosthesis being not less than $2d$, where d is the inner diameter of the shell.

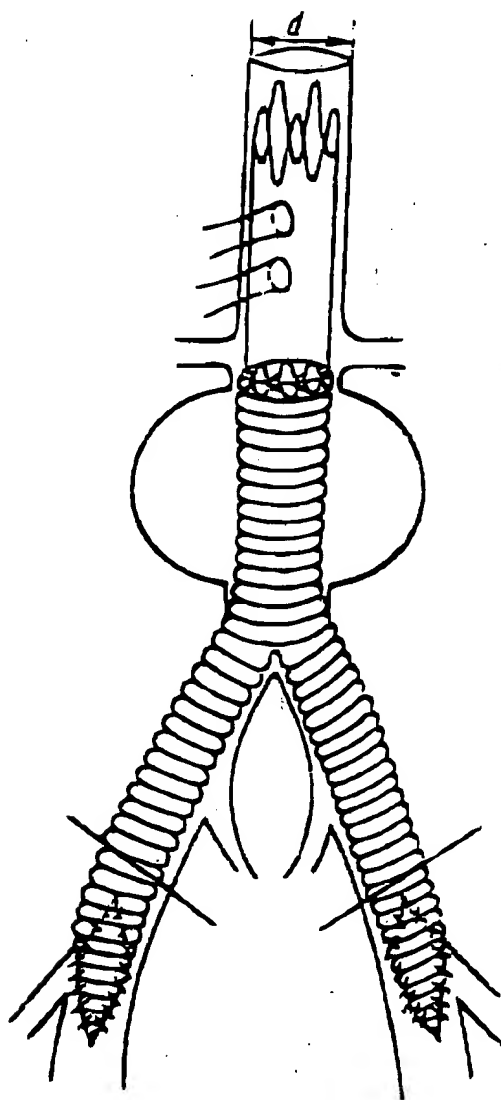


Fig. 2

(Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). >See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modern with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.")<

NONPREFERRED EMBODIMENTS CONSTITUTE PRIOR ART

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to * an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that, while the reference did teach away from using epoxy, the "teaching away" was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.).

2124 Exception to the Rule That the Critical Reference Date Must Precede the Filing Date

IN SOME CIRCUMSTANCES A FACTUAL REFERENCE NEED NOT ANTEDATE THE FILING DATE

In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. Some specific examples in which later publications showing fac-

tual evidence can be cited include situations where the facts shown in the reference are evidence "that, as of an application's filing date, undue experimentation would have been required, *In re Corneil*, 347 F.2d 563, 568, 145 USPQ 702, 705 (CCPA 1965), or that a parameter absent from the claims was or was not critical, *In re Rainer*, 305 F.2d 505, 507 n.3, 134 USPQ 343, 345 n.3 (CCPA 1962), or that a statement in the specification was inaccurate, *In re Marzocchi*, 439 F.2d 220, 223 n.4, 169 USPQ 367, 370 n.4 (CCPA 1971), or that the invention was inoperative or lacked utility, *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974), or that a claim was indefinite, *In re Glass*, 492 F.2d 1228, 1232 n.6, 181 USPQ 31, 34 n.6 (CCPA 1974), or that characteristics of prior art products were known, *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962)." *In re Koller*, 613 F.2d 819, 823 n.5, 204 USPQ 702, 706 n.5 (CCPA 1980) (quoting *In re Hogan*, 559 F.2d 595, 605 n.17, 194 USPQ 527, 537 n.17 (CCPA 1977) (emphasis in original)). However, it is impermissible to use a later factual reference to determine whether the application is enabled or described as required under 35 U.S.C. 112, first paragraph. *In re Koller*, 613 F.2d 819, 823 n. 5, 204 USPQ 702, 706 n.5 (CCPA 1980). References which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made. *Ex parte Erlich*, 22 USPQ 1463 (Bd. Pat. App. & Inter. 1992).

2125 Drawings as Prior Art

DRAWINGS CAN BE USED AS PRIOR ART

Drawings and pictures can anticipate claims if they clearly show the structure which is claimed. *In re Mraz*, 455 F.2d 1069, 173 USPQ 25 (CCPA 1972). However, the picture must show all the claimed structural features and how they are put together. *Jackmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928). The origin of the drawing is immaterial. For instance, drawings in a design patent can anticipate or make obvious the claimed invention as can drawings in utility patents. When the reference is a utility patent, it does not matter that the feature shown is unintended or unexplained in the specification. The drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art. *In re Aslanian*, 590 F.2d 911, 200 USPQ 500 (CCPA 1979). See MPEP § 2121.04 for more information on prior art drawings as "enabled disclosures."

PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based

PATENTABILITY

2126.01

on measurement of the drawing features are of little value. However, the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977) ("We disagree with the Solicitor's conclusion, reached by a comparison of the relative dimensions of appellant's and *Bauer's* drawing figures, that *Bauer* 'clearly points to the use of a chime length of roughly 1/2 to 1 inch for a whiskey barrel.' This ignores the fact that *Bauer* does not disclose that his drawings are to scale. ... However, we agree with the Solicitor that *Bauer's* teaching that whiskey losses are influenced by the distance the liquor needs to 'traverse the pores of the wood' (albeit in reference to the thickness of the barrelhead)" would have suggested the desirability of an increased chime length to one of ordinary skill in the art bent on further reducing whiskey losses." 569 F.2d at 1127, 193 USPQ at 335-36.)

2126 Availability of a Document as a "Patent" for Purposes of Rejection Under 35 U.S.C. 102(a), (b), and (d)

THE NAME "PATENT" ALONE DOES NOT MAKE A DOCUMENT AVAILABLE AS A PRIOR ART PATENT UNDER 35 U.S.C. 102(a) or (b)

What a foreign country designates to be a patent may not be a patent for purposes of rejection under 35 U.S.C. 102(a) and (b); it is the substance of the rights conferred and the way information within the "patent" is controlled that is determinative. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958). See the next paragraph for further explanation with respect to when a document can be applied in a rejection as a "patent." See MPEP § 2135.01 for a further discussion of the use of "patents" in 35 U.S.C. 102(d) rejections.

A SECRET PATENT IS NOT AVAILABLE AS A REFERENCE UNDER 35 U.S.C. 102(a) or (b) UNTIL IT IS AVAILABLE TO THE PUBLIC BUT IT MAY BE AVAILABLE UNDER 35 U.S.C. 102(d) AS OF GRANT DATE

Secret patents are defined as patents which are insufficiently accessible to the public to constitute "printed publications." Decisions on the issue of what is sufficiently accessible to be a "printed publication" are located in MPEP § 2128 - § 2128.01.

Even if a patent grants an exclusionary right (is enforceable), it is not available as prior art under 35 U.S.C. 102(a) or (b) if it is secret or private. *In re Carlson*, 983 F.2d 1032, 1037, 25 USPQ2d 1207, 1211 (Fed. Cir. 1992). The document must be at least minimally available to the public to constitute prior art. The patent is sufficiently available to the public for the purposes of 35 U.S.C. 102(a) or (b) if it is laid open for public inspection or disseminated in printed form. See, e.g., *In re Carlson*, 938 F.2d at 1037, 25 USPQ2d at 1211 ("We recognize that *Geschmacksmuster* on display for public view in remote cities in a far-away land may create a burden of discovery for one without the time, desire, or resources to journey there in person or by agent to observe that which was registered under German law. Such a burden, however, is by law imposed upon the hypothetical person of ordinary skill in the art who is charged with knowledge of all contents of the relevant prior art."). The date that the patent is made available to the public is the date it is available as a 35 U.S.C. 102(a) or (b) reference. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958). But a period of secrecy after granting the patent has been held to have no effect in connection with 35 U.S.C. 102(d). These patents are usable in rejections under 35 U.S.C. 102(d) as of the date patent rights are granted. *In re Kathawala*, 9 F.3d 942, 28 USPQ2d 1789 (Fed. Cir. 1993). See MPEP § 2135 - § 2135.01 for more information on 35 U.S.C. 102(d).

2126.01 Date of Availability of a Patent As a Reference

DATE FOREIGN PATENT IS EFFECTIVE AS A REFERENCE IS USUALLY THE DATE PATENT RIGHTS ARE FORMALLY AWARDED TO ITS APPLICANT

The date the patent is available as a reference is generally the date that the patent becomes enforceable. This date is the date the sovereign formally bestows patents rights to the applicant. *In re Monks*, 588 F.2d 308, 200 USPQ 129 (CCPA 1978). There is an exception to this rule when the patent is secret as of the date the rights are awarded. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958).

Note that MPEP § 901.05 summarizes in tabular form dates of patenting for many foreign patents. *Chisum*, Patents § 3.06[4] n.2 gives a good summary of decisions which specify reference availability dates for specific classes of foreign patents. A copy of *Chisum* is kept in the law library of the Solicitor's Office and in the Lurabelle F. Parker, Sr., Memorial Law Library located in CPK1-520.

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